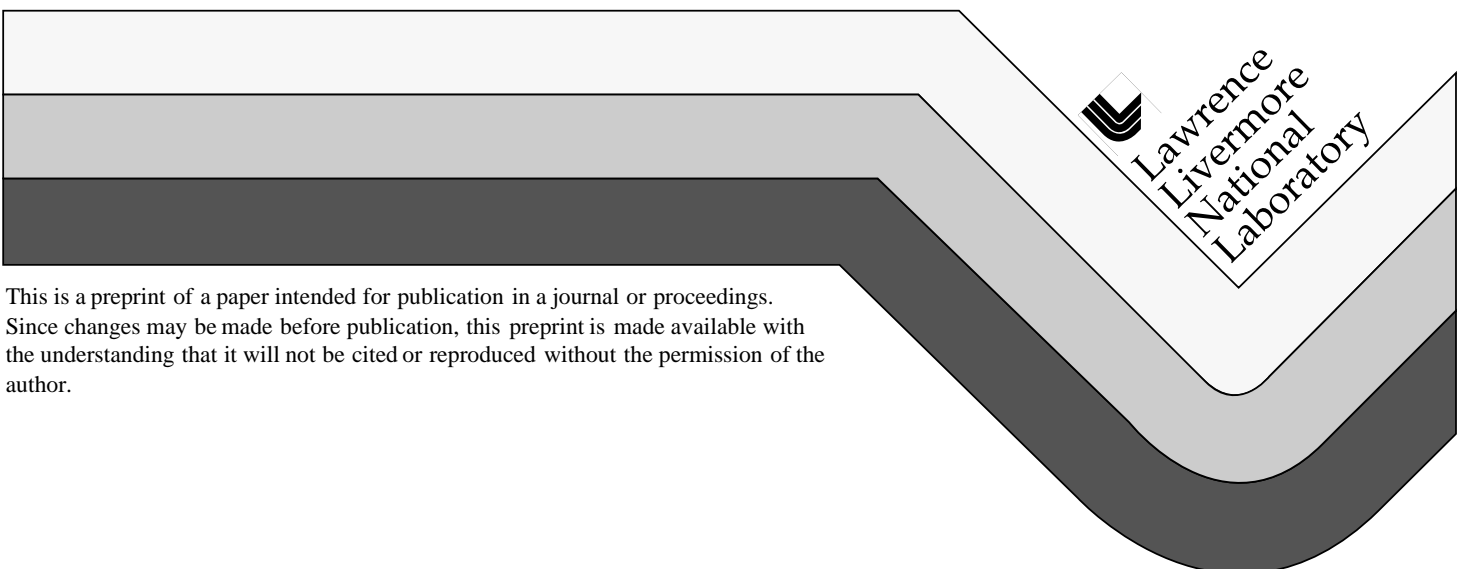


## **DOE O 414.1 Training Briefing for 10 CFR 830.120 and DOE 414.1**

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DOE O 414.1 TRAINING BRIEFING  
FOR  
10 CFR 830.120 AND DOE 414.1

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QUALITY AND SAFETY MANAGEMENT  
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## **I. Introduction**

### **Purpose**

This booklet familiarizes the reader with DOE's Quality Assurance Rule and Order.

### **Premise of the Training Briefing**

Underlying this Training Briefing is the premise that the Rule and Order have antecedents going back to the original Quality Assurance Programs that were written when nuclear power was just being developed for commercial purposes. While a lot has changed since then, much has not.

## **II. Historical Context**

### **A. The Price-Anderson Act**

Until 1954, only the federal government could develop nuclear power. The Atomic Energy Act of 1954 radically changed that by allowing private industry to participate in the development. This brought about a new problem, namely, who would be liable for injuries resulting from a nuclear accident. The financial consequences of a nuclear accident were not well known at the time, but industry estimated potential damages to be in the hundreds of millions of dollars. The specter of liability was a major roadblock for private industry's participation in nuclear power development, for they were unwilling to risk bankruptcy in the event of a nuclear accident, even if the probability of such an accident was remote (Rocket and Munzer 1973, 1-2).

The Price-Anderson Act of 1957 solved the problem. It had a two-fold purpose:

First, to protect the public by assuring the availability of funds for the payment of claims arising from a catastrophic nuclear accident. Second, to remove a deterrent to private industry participation in the atomic energy program which flowed from the threat of tremendous potential liability claims (U.S. Congress, Joint Committee on Atomic Energy 1966, 6).

The original Price-Anderson Act expired on August 1, 1967. It had been hoped that after ten years, the Act would become unnecessary because private insurance companies would have accumulated enough experience with nuclear power and sufficient capital to cover claims (Brownstein 1984). However, the Act was extended for another ten years, and in 1975 for yet another ten years, to 1987 (Brownstein 1984).

In 1988, the Act was again extended, but this time there was a new condition attached to the renewal of the Department of Energy's authority to indemnify its contractors. Congress mandated a new and separate program that subjected

contractors to penalties if they violated prescribed standards pertaining to nuclear safety (LANL 1997). This new program is now carried out by DOE.

## **B. Quality Assurance: External**

This section provides the historical context for DOE's Quality Assurance Rule and Order and answers two questions: where does the Rule and Order come from, and why was it written? Underlying the purpose of this section is the notion that the Rule and Order can only be understood—and hence effectively applied—when both its intent and meaning are understood. The Rule and Order's intent and meaning are a function of its history.

The Quality Assurance Program that is embedded in the Rule and Order has a unique historical context comprising a sequence of events that occurred in uncommon circumstances. These events began when nuclear power ceased being the exclusive domain of the federal government and was made available for commercial development. The Quality Assurance Program was born in response to regulators' concern for the public's safety from so unique an energy source, and in response to a fledgling industry's need for stability and uniformity. These two objectives led to a quality assurance program whose content has been defined by the formal adjudication of conflicts that arose from specific applications.

### ***The Atomic Energy Act of 1954***

The idea that nuclear power should be commercially developed and exploited became a national objective when President Dwight D. Eisenhower signed the Atomic Energy Act of 1954 into law. A discussion of the Act's history and provisions is beyond the scope of this text, but one of its features is germane to our subject, that is, the regulatory responsibility that the Act vested in the Atomic Energy Commission (AEC).

Even though the Act's overriding thrust was to develop a viable commercial nuclear industry, at an early point it was recognized that “nuclear technology posed a unique threat to the public welfare, and that any proposal to move it into the public domain must include some regulatory provision” (Rolph 1979, 28). The Act therefore provided the AEC with a regulatory process the principal parts of which were the AEC's licensing power and its authority to make rules (Rolph 1979, 29).

Both the industry that the Act spawned and the rules and regulations that it required were, in 1954, in their infancy. But as the industry developed and as the AEC gained experience in its role as regulator, a hierarchical set of practices and rules evolved.

### ***10CFR50 Appendix A : General Design Criteria for Nuclear Power Plants***

An early concern of both regulators and the budding nuclear power industry was the lack of standardization of nuclear plant design (Rolph 1979, 65; Campbell 1988, 32). This lack of standardization resulted in case-by-case license hearings in which each application of requirements was unique. The situation made adjudication

subjective, caused delays in licensing, and made it difficult to estimate schedules and costs of nuclear power plants (Rolph 1979, 67).

In those early days, it was difficult to develop a standard set of design criteria. On the one hand, there simply was not enough information on which to base any design, and on the other, what information did exist was changing rapidly as a result of research and development programs conducted and sponsored by the AEC.

Caught between an increased demand from the industry for design standards and the lack of information to develop meaningful ones, the AEC's regulatory staff compromised and wrote a series of general design criteria (Rolph 1979, 66; Anderson 1976, 4). In July 1967 the AEC formalized the standards development process by placing the "General Design Criteria for Nuclear Power Plants" (Appendix A of Part 50 of Title 10 of the Code of Federal Regulations) in the Federal Register for public comment. After several revisions based on public review and comment, Appendix A was issued as a formal regulation in February 1971. Thus was codified a set of general design criteria for nuclear power plants.

#### *10CFR50 Appendix B : Quality Assurance Requirements for Nuclear Power Plants*

The 1967 draft of Appendix A, discussed above, required utilities to include a description of their QA program in their applications to build and operate nuclear power plants. This was the first time that the AEC had made such a requirement (Altman et al. 1984, 1-7; Langston 1991). The requirement was very general, however, as the regulatory staff had not yet finalized the criteria with which to evaluate QA programs (Altman et al. 1984,1-7).

On September 17, 1968, the Atomic Safety and Licensing Board (ASLB) suspended the hearings for an operating license for Unit 2 of the Zion nuclear power plant (Altman et al. 1984, 1-7; Langston 1991). The ASLB "ruled that until the licensee presented a program to assure quality and until the AEC developed criteria by which to evaluate such a quality assurance program, the hearings would be halted" (Altman et al. 1984, 1-7). The AEC promptly established a task group to write criteria with which to evaluate QA programs (Langston 1991). This task group drafted a QA document, based on the QA experience of the AEC, the Department of Defense, and the National Aeronautics and Space Administration (Altman et al. 1984, 17; Muller 1984, 18; Langston 1991). The document was published for public and industry review in the Federal Register on April 17, 1969. On June 27, 1970, after completion of the review cycle, the QA document was formally issued as "Quality Assurance Requirements for Nuclear Power Plants," which is Appendix B to Part 50 of Title 10 of the Code of Federal Regulations,

10CFR50 Appendix B is the formal regulatory requirement for QA programs and is applicable to the design, construction, and operation of nuclear facilities. It contains 18 criteria that collectively constitute a QA program. When properly implemented, this program will provide adequate confidence to the regulators that a structure, system, or component will perform satisfactorily in service.



## **C. Quality Assurance: Internal**

The discussion above pertains to Quality Assurance Programs for organizations in the business of designing and constructing nuclear power plants. The AEC and its successor agencies also developed Quality Assurance Programs for internal use. On December 12, 1973, the AEC published a new Chapter 0820, "Quality Assurance," in part 0800 (Management Principles and Techniques) of the AEC Manual. The policy statement in it read:

It is the policy of AEC that effective written quality assurance programs shall be established and implemented for all AEC programs. Positive emphasis and attention to quality assurance by responsible AEC and contractor management are essential to achieving an effective program (AEC 1973).

All AEC activities included in Chapter 0820's scope must have written quality assurance programs, use a graded approach in implementing QA, and include certain key elements. These elements include: assignment of organizational responsibility for quality assurance, a process for specifying the level of quality for specific work, procedures for implementing the program, and an independent system for verifying compliance with and adequacy of the quality assurance program. The chapter also identifies eighteen optional QA requirements. It may be observed that the internal quality assurance requirements almost matched those of the external ones.

On May 24, 1979, then Secretary of Energy James R. Schlesinger issued a memorandum establishing a study group, designated the DESM 79-2 Study Group, "...to develop a detailed implementation plan for instituting a strong quality assurance/quality control program..." (Schlesinger 1979). The group developed a Draft Order on Quality Assurance dated April 15, 1980. A series of reviews, comments, and revision cycles ensued, and on January 1, 1981, the Department of Energy issued DOE Order 5700.6, which contained the underlying principles of a QA program, but did not specify criteria for application. The order went through three revisions (revision A was issued on August 13, 1981, revision B on September 23, 1986, and revision C on August 21, 1991). Revisions A and B included a reference to the ANSI/ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities," the nuclear industry's equivalent of 10CFR 50 Appendix B, discussed above (DOE 1981, Attachment A; DOE 1986, 5). Thus DOE's internal and external quality assurance programs intersected with these two revisions. The order's third revision was different.

## **III. Current Quality Assurance Program Structure**

DOE Order 5700.6C was different from its predecessors. The previous revisions were made more in the nature of lessons learned and editorial refinements. This revision signaled a significant change in direction. With it, DOE tried to distance itself from the traditional way in which quality assurance had been perceived and

executed by the Department's elements; it began to align itself with contemporary quality principles used in industry.

Three themes underlie the revised quality assurance program. Recognizing them is fundamental to understanding the Order:

1. All work is a process that can be planned, performed, assessed, and improved.
2. All work can be divided into three categories. They are: management, performance, and assessment.
3. Each of work's three categories in turn can be divided into a total of ten functional criteria which collectively "comprise the foundation of a comprehensive quality assurance program." (DOE 1991, Attachment I, 1).

The first theme is intended to be all-inclusive. Everything done to further an organization's mission can be planned, performed, assessed, and improved. The second theme

permits managers, those performing the work and those assessing the planning, implementation, and results of the work to focus on their unique responsibilities in carrying out the provisions of the quality assurance program (DOE 1992a, 5).

The third theme expresses the view that the quality assurance program's provisions define a complete quality assurance system. Therefore, every directive and requirement, whether originating from the Department, state, or local agencies, indeed, even requirements internal to the organization, may be associated with one or more of the quality assurance program's ten functional criteria. That being the case, these criteria may be used to evaluate existing QA programs—developed to comply with sponsor and regulator requirements—and integrate all the requirements placed on the organization, determine whether applicable criteria have been implemented, eliminate redundancies, and determine how well the various programs integrate into a comprehensive whole.

The quality assurance program requires no additional QA documents if existing ones comply with imposed requirements and with DOE Order 5700.6C. (DOE 1992b, 6; DOE 1992a, 5). If one or more quality assurance program criteria are not included in the existing programs because they are not applicable, the quality assurance program does not require development of documents to include these criteria. The format of any existing system can stand; format is irrelevant to the quality assurance program. Content is what matters.

The quality assurance program defines quality and quality assurance in a way that has significant implications. Previously, no DOE Order ever contained a definition of quality. They do now: "Quality [is] the degree to which an item or process meets or exceeds the user's requirements and expectations" (DOE 1991, 3). It follows that "Quality Assurance [is] actions that provide confidence that quality is achieved" (DOE, 1991, 3). If "the user's requirements" are defined as the

requirements imposed on a program by its sponsors or regulators, then “quality” means meeting or exceeding those requirements. Quality assurance in this context means a program formulated and implemented to provide confidence that requirements are met.

The most recent DOE Quality Assurance order, DOE O 414.1, continues on the path of DOE Order 5700.6C. It also views the Quality Assurance Program as a management system where work must be planned, performed, assessed, and improved, and where the three categories of work—management, performance, assessment—are subsumed in the ten functional criteria.

## **The Graded Approach**

The implementation of the quality assurance program uses a graded approach. This means that in applying generally stated requirements to specific activities, a judgment is made to determine just how much effort should be expended to meet those requirements. That judgment is based on an assessment of the risks involved. The greater the risk, the more formal and rigorous the planning for the activity, the more controls placed on the activity during its execution, the more careful the actual performance of the activity, the more closely the activity is assessed, and the more formal the record-keeping.

The graded approach is thus based on perceived risks that go with the activities being contemplated. All manner of techniques may be invoked to determine an activity’s risk. In the end, however, successful application of the graded approach depends on “available information, existence and knowledge of the effectiveness of physical and administrative controls, and the experience of the assessor” (LLNL 1993, 3).

## **IV. Requirements**

### **A. General**

#### ***Definition:***

Quality Assurance Program or QAP means the overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

(10 CFR Part 830, Paragraph 830.3: Definitions)

#### ***Statement of Quality Assurance Requirements:***

A contractor shall develop a QAP by applying the quality assurance criteria specified in paragraph (c) of this section [these are the ten criteria that are discussed below]. A QAP shall include a discussion of how the criteria of paragraph (c) of this section shall be applied using a graded approach. The contractor shall use appropriate standards, wherever applicable, to develop and implement its QAP.

(10 CFR Part 830, Subpart A, Paragraph 830.120 [B])

***Key Points:***

- a. Every contractor doing work within the scope of the Order or Rule must have a QAP.
- b. The QAP must contain the ten criteria outlined below.
- c. It is not sufficient to merely copy the ten criteria into the QAP. The QAP must describe how the criteria are used.
- d. A graded approach is used to implement the ten criteria.
- e. Where appropriate, existing quality assurance programs can be used if they are accepted as standard.

***Discussion:***

The Rule applies to activities at DOE nuclear facilities. The Order extends the applicability to activities of DOE departmental elements and those of “. . . all contractors responsible for management and operation of DOE-owned or -leased facilities (including work, such as design or manufacturing, which may take place outside the physical boundaries of a DOE facility)” (DOE 1998, 1). Organizations within the scope of the Rule and Order must have a program that identifies who is in charge, who does the work, and who checks the work. In addition, a QAP includes policies and procedures. The policies must articulate the intent to comply and the procedures must describe how that intent is carried out down to the working level.

## **B. Management Criteria**

### **Criterion 1—Program**

***Requirement:***

A written QAP shall be developed, implemented and maintained. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QAP shall describe the management processes, including planning, scheduling, and resource considerations.

***Key Points:***

- a. This reiterates the requirement stated in the general part of the Rule, cited above: every organization within the scope of the Rule or Order must have a quality assurance program and it must be documented.
- b. The organization’s structure and its processes must be made visible.

***Discussion:***

This first criterion—a document describing an organization’s quality assurance program—does three things. It commits the organization to compliance with the Rule and the Order. It explains the organization, making it visible. Finally, it is a

guide that explains what is expected from lower-tier organizational units for the implementation of a QA program

The QAP document must be consistent with the requirements of the Rule and the Order, which means that all ten criteria and the graded approach must be included in it. This means that the other nine criteria must first be developed before the QAP document can be written. The QAP document may be the first requirement, but it is fulfilled last.

A QAP document should provide both a context and description of the organization. The mission, end products, or performance objectives are an organization's context. Its description can be derived from defining its "organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work." Some of this can be done with an organizational chart, which easily makes visible structures, responsibilities, and levels of authority. The chart can be augmented with brief descriptions of the responsibilities covered by each block of the chart, and with descriptions of interfaces among them.

To fulfill its purpose as a description of an organization's quality assurance program, a QAP should include a discussion of all ten criteria as well as a description of the graded approach as they are interpreted by the organization. To accomplish its goal as a guide, the QAP ought to make clear what the organization's expectations are for the implementation and formalization of its QAP, at least at the departmental level. Some criteria may be implemented by the institutional level only, e.g., Criterion 10, "Independent Assessments." For them, the lower-tier units are guided with a description of how they link with the organization-wide system in fulfilling this requirement. Other criteria are partially implemented by the institution and partially by the lower tiers, e.g., Criterion 2, "Personnel Training and Qualification." In these cases, the lower-tier units must be provided with guidance on what is expected of them and how their implementation is related to the organizational implementation. The QAP delineates which requirements are to be implemented by which organization.

There is no requirement for QAP documentation below the institutional level. Nevertheless, departments or divisions and even some operations may find it practical to have lower-level QAPs. The reasons for this are varied and ought to be spelled out in the specific QAP. One reason may be a work sponsor's imposition of such a requirement.

All QAPs are implemented at the working level through written procedures. QAPs delineate in some detail what must be done and who must do it. Procedures emphasize how the work must be done. Procedures are an alternative to having a lower-tiered QAP; they may be developed straight from the requirements spelled out in a higher-tiered QAP. Note that this in effect adopts the higher-level QAP with its ten criteria, which may not be necessary for the lower-tier work. For example, if the activity does not involve any design work, then Criterion 6, "Design," does not

apply and can be left out. It is the graded approach that dictates what must be addressed and to what extent.

## **Criterion 2—Personnel Training and Qualification**

### ***Requirement:***

Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained.

### ***Key Points:***

- a. People who are assigned work must know how to do that work.
- b. Training programs exist to assure continued ability to do the work.

### ***Discussion:***

This is a straightforward criterion applying only to job-related training and qualification. It does not apply to educational opportunities, continuing education, career development, and other training not specifically related to a job assignment.

The training related to a job assignment usually has two components: base-skills training and assignment-specific training. Base skills are the fundamental skills required for a particular type of work. An employee must have relevant base skills to qualify for a job. Assignment-specific training provides an employee with skills beyond the base level, that are specifically required for a particular assignment.

## **Criterion 3—Quality Improvement**

### ***Requirement:***

Processes to detect and prevent quality problems shall be established and implemented. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items, services and processes needing improvement.

### ***Key Point:***

There are three ways to improve quality, and all three should be part of a quality improvement program:

- a. Establish processes that detect problems.
- b. Establish processes that prevent repetition of known problems.
- c. Scrutinize operations data for opportunities to improve quality processes.

### *Discussion:*

This third criterion states that any program can improve the quality of its operations in three ways: 1) detect problems as soon as they occur and act to correct them as soon as they are discovered; 2) once a problem is discovered, the correction should be such that it cannot happen again, that is, learn the lesson; 3) establish a requirement that operations data is reviewed and analyzed to see if processes can be improved even though everything is running as planned.

Problem Detection. In spite of best efforts, problems happen. With this in mind, quality programs usually include processes designed to detect and correct problems as soon as they occur. Typically such processes include the following provisions: every person working within the scope of the quality assurance program is empowered to report problems wherever and whenever they are discovered; there is a central administrative center to which problems are reported and which is charged with the subsequent handling and monitoring of problems until resolution; problems must be investigated and their root cause identified and eliminated. These provisions have ramifications for administrative network necessary to implement them. To illustrate the potential extent of the ramifications, consider what a quality improvement program typically entails.

First, a training or orientation session for all hands is usually necessary to acquaint employees with the problem detection program in general, and the method for reporting problems in particular. A careful definition of what constitutes a problem is required. Second, a special form to report problems must be available. Third, there must be a center to which reports are directed. Fourth, people must know what their responsibilities are beyond reporting when a problem is discovered. These may include: authority to stop work, quarantine defective items, or suspend work immediately in those cases where there is an imminent hazard or significant adverse economic impact. Fifth, there must be a root cause analysis of the problem, involving investigative techniques and reporting requirements. And finally, sixth, there must be administrative procedures for problem closure and dissemination of lessons learned so future occurrences of the same problem are prevented.

The administrative center charged with handling reported problems has essentially three functions:

1. It is the collection point for all problems.
2. Once it is notified of the problem, it monitors progress toward problem resolution.
3. It assures that, once resolved, the problem and the actions toward its resolution are a matter of record.

The administrative center is largely a bookkeeping function, but one that is crucial to the success of the quality improvement program.

Problem investigation is usually assigned to an individual or (cross-functional) teams with the requisite expertise and knowledge to resolve the problem as well as the authority to implement the solution. (At times, finding the solution and implementing it may be done by two different parties.)

Items that are defective or cannot be used require decisions on what to do with them. Work that does not result in an anticipated goal require decisions on how, what, and when to change procedures.

Problem Prevention. Eliminating a problem's root cause to prevent its recurrence is one preventive measure. There are, however, other preventive measures that can be taken before a problem even occurs. These are typified by peer reviews, design reviews, risk assessments, safety analyses, or process analyses, which work to determine how processes can be controlled, what portions of them should be controlled, and how stringent the controls ought to be. This approach to problem prevention attempts to anticipate what the problems are going to be, determine the consequences should the problems occur, and, if the consequences are unacceptable, take steps to prevent them from occurring. The graded approach is useful in this approach. And once the preventive measures are in place, they are monitored for whether the work is proceeding as anticipated, whether the problems are as predicted, whether the controls are as stringent as need be or are too stringent.

Continuous Quality Improvement. The underlying premise of continuous quality improvement is that work can always be done better. It asks the question, "How can we do things better even though everything is going fine and there are no unexpected problems?" The question should be posed by everyone in the entire organization, because everybody contributes to an organization's effort.

In addition to good ideas from people, continuous quality improvement benefits from gathering and analyzing data about processes, problems encountered, item failures, procedural inadequacies, or process improvements. For programs large and of long enough duration, the data could be subject to trend analysis. Periodic meetings could be held to review these data and their relevance to improvements across the organization.

#### **Criterion 4—Documents and Records**

##### ***Requirement:***

Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.

##### ***Key Point:***

This criterion addresses two separate but related sets of controls:

- a. One calls for controls governing the preparation, distribution, and revision of documents that prescribe how work is done.



- b. The other calls for controls governing the identification, retention, and retrieveability of records that can attest to how work was done.

**Discussion:**

It has been pointed out that contemporary quality assurance emphasizes performance over compliance, although compliance has not been wholly eliminated. This criterion's roots are in the compliance aspects of the QAP. It requires, subject to application of the graded approach, programs or projects to write down what they do and how they do it, and preserve records of what was done in order to demonstrate compliance with procedures, rules, and regulations.

This criterion must be addressed with two thoughts in mind: the difference between documents and records, and how much document and record control is necessary, in keeping with the graded approach.

In this discussion, a document is written or pictorial information that informs the reader of how work must be done, as for example, a procedure or an up-to-date engineering drawing. A record, on the other hand, is a completed document, one that will no longer be used or receive additional entries. A superseded procedure is a record, as is a set of 'as-built' drawings. At its most basic definition, a document is in use while a record is not (Battelle Memorial Institute 1989, 4 and 9).

A typical quality program specifies the development and implementation of a document control system in great detail. Correct implementation of such a system assures that:

1. Procedures are written by those who know the work activity—qualified people.
2. Procedures are reviewed by those who know the work activity and did not write the procedures—qualified and independent people.
3. Procedures are approved by those who are responsible for the work activity, usually managers, or those with program or project fiscal responsibility.
4. Procedures are sent to those who must use them.

If it is important enough to write down, it may be important enough to save. Records are kept to provide evidence that goals—program, project, safety, or other, perhaps regulatory, goals—have been met. They preserve the basis of work activities, the method by which work was accomplished, and management judgments. A retention system should be planned for records, and part of the planning should consist of determining which documents will be important enough to become records. It may be difficult to make such an *a priori* determination; the QAP can be looked to for guidance. Additionally, the record record-keeping system should include methods for collecting, filing, storing, and retrieving them, and the time frames for these activities.

The Graded Approach. The extent of documentation and related record control depends on the nature of the work. If it is a collaboration between two scientists, there probably would be no great need for work procedures. The two peers could simply engage in an open, fluid exchange of ideas, based on sharing the same assumptive framework, training, and experience.

However, if their experiment were to exceed the safety boundaries of the facility in which it is being conducted, then facility management may want a written procedure so it can review the proposed work. Or, if the experiment is successful and expanded—more money, more people, more equipment—then it may become necessary to start writing procedures for the control and integration of the various functions of the experiment now about to become a project.

The determination of whether to keep records is somewhat independent of the decision whether or not to write procedures. The two scientists may want to keep records of their work even if they decide not to write any procedures. However, the system devised to make sure records are properly collected and kept is, once again, dependent on the nature and complexity of the task. The scientists may decide to keep records in a filing cabinet where all the other laboratory notebooks are kept. The rigor of controls is a function of the risk and complexity of the documentation subject matter. The tradeoff is between utility and paperwork burden.

There is a structural question associated with this criterion. Where are these document and record control systems organizationally located? Often organizations decide to establish a central document control system and a centralized records system. They are perhaps easier to manage and more cost effective.

## **C. Performance**

### **Criterion 5—Work Processes**

#### ***Requirement:***

Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.

#### ***Key Points:***

- a. Work is controlled by either standards or written instructions.
- b. Tools and machinery used in work are controlled.
- c. Materials used for work are controlled.
- d. Measuring and test equipment used in work are controlled.
- e. In developing administrative or other controls for work, the graded approach is used to relate effort and cost with risks involved and benefits gained.

### *Discussion:*

As previously mentioned, the ten criteria of the Rule and Order are organized in three categories: management, performance, and assessment. The criteria that fall under the performance category control work directly, while the criteria of the other two categories may be said to be one step removed from work: they control the work controls. To an extent larger than is true for the management and assessment criteria, performance category controls are dependent on the activity to which they are applied.

Criterion 5 is the broadest of the direct work control criteria; it pertains to work in general, that is, the actual process of transforming inputs into outputs. There are many types of work: conducting experiments, designing equipment, constructing buildings, issuing paychecks, delivering training, and a host of others. This criterion is about all those. It requires that work be prescribed to the extent the graded approach determines it must be controlled. What are the elements of work controls? In general, they are people, equipment, materials, methods, and measurements.

People. People who do the work must be qualified. This requirement is stated in Criterion 2, Personnel Training and Qualification, which prescribes job qualifications based on the nature of the work and whether it requires basic skills or special training. That in turn determines the controls necessary to ensure appropriately qualified personnel for the work.

Equipment. The term equipment encompasses things from expensive, complex pieces of machinery to individual measuring tools. Quality assurance of equipment must consider what equipment is necessary for the work at hand, how it must be maintained or stored, whether procedures are necessary to assure that the equipment is operated or handled correctly, and whether it is necessary to assure that the equipment is not used for other work. These issues suggest necessary equipment controls. This criterion particularly singles out equipment used to monitor processes or collect data. Whether they require calibration and if so, how often and by whom, is an important issue.

Materials. If a graded approach method concludes that it is important to prevent damage, loss, or deterioration of materials used during the work, then methods should be developed to accomplish this. This usually encompasses methods to identify materials, and receive, handle, use and store them correctly. If it is necessary to transport material, then methods should be developed to do that as well.

Methods. There ought to be methods prescribed for all work, and much of it should be done to standards, but not all of it must be written down. Again, the graded approach should determine what work is of sufficient complexity, hazard, or importance to warrant performance in accordance with instructions, procedures, or drawings. Once a decision is made to write instructions, procedures, or develop drawings, a second decision is necessary to determine their level of prescriptive detail. Criterion 4, Documents and Records, is used to control the writing, review,

and maintenance of procedures and instructions. Criterion 6, Design, is used to control drawings.

Measurements. Those who do the work ought to be given performance objectives. There are any number of performance objectives: quality standards, work standards, quantified customer expectations, or mutually-agreed-to performance objectives between worker and manager. Once performance objectives are identified and, when necessary, made a matter of record, feedback about work performance should be provided regularly.

Summary. Criterion 5 requires a thorough consideration of the work being contemplated. It recommends breaking work down into five components to more clearly see its risks. The Rule and Order require the graded approach to determining appropriate controls, how intensely and formally the controls should be applied, and what documents and records are necessary.

### **Criterion 6—Design**

#### ***Requirement:***

Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.

#### ***Key Points:***

- a. This criterion applies to conventional design activities. It does not, for example, apply to design of scientific experiments.
- b. Design input is appropriately specified and timely.
- c. Design interfaces are identified and controlled.
- d. Designs are verified by persons who did not create the design.
- e. Design changes are controlled by the same processes that controlled the original design.
- f. Designs are validated before they are put in place.

#### ***Discussion:***

The scope of this criterion covers activities that are subject to design control, namely, engineering design or the design of facilities or equipment. It includes software that aids design activities. It applies as well to scientific processes, for example, a process to separate chemical isotopes, or a process to reduce toxic waste, or a process to generate steam. Other types of processes, such as procurement processes, audit processes, shipping processes, or even management processes in general are not the subject of this criterion.

The controls required by this criterion exist in the standards and manuals published and maintained by professional societies and those organizations to which this Rule and Order apply. These organizations are familiar with engineering design control. The graded approach will determine to what extent these controls must be applied. These requirements control the design process:

- Description of how design inputs are converted into specifications, drawings, procedures, and instructions. Design inputs include ES&H and quality considerations.
- Description of how design changes are handled. Design changes include permanent or temporary modifications, field changes, and certain problem resolutions.
- Description of design interfaces and corresponding responsibilities. Design interfaces are the links between all the organizations involved in the design, either they are actually designing parts of the whole or providing input and support services.
- Description of the methods used to validate and verify the design. This includes validation and verification of any software used to aid in the design.
- Description of how and who approves designs.
- Description of how the final design records will be collected and archived.

## **Criterion 7—Procurement**

### ***Requirement:***

Procured items and services shall meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.

### ***Key Points:***

- a. For many organizations within the DOE complex, two sources for the acquisition of goods and services are recognized:
  - i) external (commercial) suppliers,
  - ii) internal (support) organizations.
- b. Requirements should be specified and translated into procurement documents. Procurements should be checked and verified upon delivery.
- c. Prospective suppliers should be evaluated and only qualified suppliers selected.

- d. Suppliers should be monitored periodically, to make sure they continue to provide what is required.

*Discussion:*

Most organizations treat the two procurement sources (that is, internal suppliers in support organizations and external commercial vendors) differently from a fiscal, policy, and procedural perspective. This criterion views the two sources in the same quality perspective: goods and services must meet specified requirements regardless of source. But because rules and regulations developed for external procurements do not normally apply to internal support organizations, this criterion will probably have to be modified to achieve the same result, namely, controls to assure that what is received is what was bought.

Commercial Suppliers. Procurement of goods and services from commercial suppliers is subject to numerous controls written in the Federal Acquisition Regulations, which have been adapted by DOE Acquisition Regulations and a number of DOE Orders. In addition, most organizations have policies and procedures for handling commercial procurements. All these controls and procedures may be used to meet the requirements of Criterion 7, which, like the other nine criteria, does not require the development of more procedures where existing ones already exist.

The ability to actually sign contracts with suppliers is restricted to a few officials. But the signing of contracts with suppliers is only a small part of the procurement process. Before a contract is signed the procurement should be planned, appropriate procurement documents should be written, and prospective suppliers should be evaluated. Whenever possible, the procured goods and services should be inspected and evaluated before use. These are significant activities.

This criterion requires that “steps must be taken to ensure that procured items and services meet established requirements and perform as specified.” Specifically, this usually involves the following steps:

- Procurements are planned.
- Plans are articulated into procurement documents.
- Prospective suppliers are evaluated and then selected.
- Once selected, suppliers' continued quality performance should be monitored.

It goes without saying that the graded approach is used to determine which steps are appropriate and the extent of their application.

Planning a procurement involves, among many other things, determining what prospective suppliers are going to be evaluated for. What should be required of them by way of technical and administrative acumen? Traditionally there are three methods to evaluate suppliers: historic performance, that is, a known capability (preferably buttressed by written evidence) of providing an identical or similar

product or service; current performance as may be indicated by technical and administrative (that would include quality assurance) programs; and a direct evaluation of prospective supplier's facilities, personnel, and technical and administrative programs. A combination of all three could also be used to evaluate prospective suppliers.

Once a supplier has been selected how should his or her performance be monitored? Again, several methods, and combinations of methods, have worked well. There could be regular trips to the supplier's facility to review operations. Or, what the supplier has already delivered could be subject to inspections or tests. Or, the supplier could submit specific reports which the end user could then review. Some of the methods work better with hardware, others with services, but all can be used.

Part of planning includes decisions about how goods and services are going to be accepted. Will they be inspected or tested? Will a certificate of compliance suffice? And where will goods be inspected or tested: at the supplier's facility or when the goods are delivered to the facility? How are services going to be evaluated? What steps are to be taken when the goods or services are unacceptable? For that matter, how are changes in procurement objectives going to be accommodated? All these questions, or rather, the answers to these questions, are part of procurement planning.

Finally, documentation of procurement activities is important. Obviously, the contract is part of the documentation, but so is other written evidence that the procurement process, however defined by an organization, was carried out as required.

Organizational Support Organizations. Procuring goods or services from organizational support services does not have to be as formal as when procuring from commercial suppliers, although planning for what is needed can be as rigorous. The requesting organization—the acquiring organization—is responsible for assuring that the support organization's goods or services meet specified requirements. This requires two actions on the part of the requesting organization. One, explain to the support organization what the requirements are. Two, specify methods on how its line management assures that specifications were met. The supporting organization should comply with the requesting organization's requirements.

## **Criterion 8—Inspection and Acceptance Testing**

### ***Requirement:***

Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.

*Key Points:*

- a. This criterion applies to existing items and known processes.
- b. Inspections and acceptance testing are planned ahead.
- c. A record of what was done must be made.

*Discussion:*

This criterion applies to items and processes that are in working order, but must be inspected or tested before use to determine if they meet specifications. The criterion does not apply to the exploratory testing of concepts or testing to see if a design really works.

Since most undertakings acquire items or develop processes, this criterion is likely to be included in a QAP, usually as a general description of when it should be applied and the major issues involved in its application. Its more exacting provisions are usually delineated in implementing procedures for inspecting and testing items or processes.

Why do inspections or acceptance testing? First, to see if an item or process complies with specifications. Second, to comply with requirements for facilities with critical safety and security issues, e.g., a non-reactor nuclear facility, where all components that affect a facility's safety system must be inspected before installation. Similarly, when the failure of items or processes could cause expensive rework or schedule delays, a specific application of this criterion is desirable. In general, inspections and testing should be performed on items and processes important enough to warrant the time and effort.

Inspection and acceptance testing are activities that are planned ahead of time. Once it has been decided that an inspection or testing must be performed, the inspection or test criteria must be determined, and the protocols and measurements delineated. Other planning considerations include the timing of inspection and testing—should it be done when an item is completely manufactured, or when specific components are done? When a process is complete, or can portions of it be tested before hand? Before the item is shipped, or when it arrives at the loading dock? Before or after installation? While it is operating, or after the operation is stopped? Furthermore, decisions must be made about when an item or process acceptable, or what happens when an item or process is rejected. The answers are usually provided by acceptance testing procedures.

Inspection and test procedures, which include acceptance criteria, should be written by the same people who designed the item or process, or who are going to use them. However, the inspection or test itself should be done by those independent of their design, development, and manufacturing.

The Criterion 5 statement that workers should inspect their own work applies to inspections to determine whether the work process is in control and producing acceptable output; it does not apply to inspections for acceptance. That is up to the customer.



Operational readiness reviews is a subset of this criterion. Readiness reviews pertain to entire systems, not just to items and individual procedures. The planning and preparation for operational readiness reviews follow a similar cause-and-effect process as for inspections and acceptance testing, but the scope and complexity are obviously much greater.

Documentation of the inspections and acceptance testing is important. Normally inspection or testing is done when the risks of not doing them exceed their effort and cost. In such cases, records are useful for demonstrating that inspections and tests were done correctly, or, when an unforeseen event happens, used to determine what could have been done to prevent it. A QAP should require that adequate records be kept of inspections and tests.

Often, inspections and acceptance tests require measuring and special test equipment. This criterion requires such equipment to be properly calibrated and maintained.

## **D. Assessment**

### ***Definition:***

DOE O 414.1 (Draft 2, dated May 19, 1998) defines assessments as follows:

Assessment/Verification. The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. The terms assessment and verification, as used here, are synonymous; their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are performed by the line organization.

## **Criterion 9—Management Assessment**

### ***Requirement:***

Managers shall assess their management processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

### ***Key Points:***

- a. Management assessments are done by those who manage the work they are assessing (in other words, they are not independent assessments).
- b. Management assessments are concerned with broad organizational issues.

### ***Discussion:***

Criterion 9 institutionalizes a tenet that has been expressed in all traditional textbooks on management: managers evaluate their areas of responsibility for progress toward the planned objective; they make course adjustments as necessary.

This is self-assessment, for managers themselves evaluate and check the work for which they are responsible. The literature on quality and quality improvement programs provides a popular model for this assessment, described as the Plan-Do-Check-Act cycle. To plan is to establish a way or a standard for achieving an agreed-upon goal; to do entails the enacting of the plan; to check is to measure or analyze the results after the plan has been put in practice; and to act means implementing the necessary reforms when the results are not as planned. Self-assessment consists of the manager checking his or her area of responsibility and measuring and analyzing results.

Management self-assessments are not concerned primarily with compliance to regulatory issues or conformance with procedures (it is probably an error to state that they are not at all concerned with compliance issues, although the temptation to state exactly that is great). Instead, management self-assessments are more concerned with the qualitative organizational issues. They should evaluate issues such as:

1. The state of worker knowledge, motivation, and morale.
2. The atmosphere of creativity and improvement.
3. The level of mutual confidence and collaboration among workers.
4. The adequacy of human and material resources.
5. Recognizing and enhancing human resource capabilities.
6. Customer expectations and the degree to which they are being met.
7. The management of ES&H in the performance of work processes.
8. Opportunities for improving quality and cost effectiveness (DOE 1992a, 19; DOE 1992b, 12).

This list, illustrative and not comprehensive, demonstrates that management assessments have far ranging scopes, and their focus is organization-wide issues.

Management should not only retain responsibility for their self-assessment program, they should actively participate in them. In fact, all levels of management ought to be involved in self-assessments. Furthermore, there are times when it would be beneficial to have non-managers involved in self-assessments. The benefit of these assessments is a good, in-depth knowledge of the workings of the entire system, not just specific functional areas.

How formal should management self-assessments be? Guidance here calls for some level of formality when warranted (the graded approach). The ER Standard provides an example of the range of appropriate response:

In a bench-scale collaboration of 2–3 scientists, evaluation may be performed by informal collaboration meetings and workshops. In larger collaborations involving over 300 scientists, evaluations are more formally documented meetings and workshops that may consist of presentations by collaboration members (DOE 1992b, 5).

There are, of course, activities with fewer than 300 participants that still require some measure of formality. Moreover, formality could be a function of the complexity or purpose of the endeavor or its purpose, e.g., proof-of-principle for continued or increased funding of a project. The level of formality cannot be prescribed; it is situation-specific.

### **Criterion 10—Independent Assessment**

#### ***Requirement:***

Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments shall have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.

#### ***Key Points:***

- a. Independent assessments are planned and scheduled activities.
- b. Independent assessments emphasize actual performance.
- c. Independent assessments are performed by those possessed of sufficient authority to assure their independence.
- d. Independent assessments are performed by those with knowledge and experience.

#### ***Discussion:***

In this criterion, managers call upon persons not associated with their work to evaluate the work. Whereas Criterion 9 asks that managers check to see if things are being done right, Criterion 10 is more concerned with whether the right things are being done. This is a more difficult thing for a manager to evaluate, immersed as he or she is in the work and the day-to-day toil of managing. Someone with a fresh perspective could better point to improvements.

Independent assessments, while they emphasize quality performance, also include a component of compliance. Determination of compliance is a vital part of all requirements, and this criterion requires independent assessors to determine whether compliance with requirements is a fact.

Use of the term “assessment” is by design. This criterion is being distanced from what used to be called independent audits. In fact, the term “assessment” subsumes a number of terms referring to activities with which many organizations have become well acquainted over the years: review, inspection, test, check, surveillance, audit, and any other term used to describe an activity that provides feedback on an organization’s performance. Over time those activities have acquired a negative connotation. “Paperwork exercises,” “nit-picking expeditions” are but two of the pejorative expressions by which these activities are known. Use of the term “assessment” signals the attempt at refocusing traditional techniques toward a more meaningful and useful purpose, namely, feedback to inform management how well—or not well—work is progressing.

Assessments are performance-based and focus on improving operations and the operations' products. As was stated earlier, assessments do not ignore the compliance component, but compliance is a secondary consideration. Performance is what matters. Performance-based assessments implies the following:

1. Assessments are performed on activities that make a difference—not trivial ones with no real impact on the facility or organizational performance.
2. Assessments are performed in a manner that emphasizes safety, reliability, and performance. Assessments and their results should pass the “so what” test to differentiate the vital from the trivial.
3. Assessments are performed by qualified personnel who have the necessary technical capabilities to observe and evaluate an activity accurately. Assessment teams should include technical peers (DOE 1992a, 20).

Assessments are formal. This criterion states that assessments should be planned. Thought must be given to what is important—what to observe or evaluate—and what kinds of measurements to use in order to make an evaluation, as well as when to do it. The allocation of people and time to the assessment work should be a function of the risk, complexity, and importance of the activity being assessed.

Assessors should be both competent and independent of the activity being assessed. An independent assessor is a person or a group with absolutely no stake in the assessment results (Crosby 1979, 79). Typically an assessment is conducted by a group with pertinent knowledge and are peers of those they are evaluating.

A good assessment perspective is one that views the assessees as customers who have asked, “How can we improve?” This places the assessors in the role of advisors and makes it easier to focus the assessment on improvement.

Assessment results should be acted upon. Positive results should be communicated so the positive activity is reinforced. Negative results should be resolved. All the steps required for their resolution should be written down and monitored, and perhaps communicated as a “lesson learned.”

One more point is important to keep in mind when planning to develop directorate-specific guidance for this criterion. The fundamental tenet of this criterion is that organizations must have their own independent assessment program, over which they have control. Independent reviews performed by outsiders over whom organizations have no control are not a response to the requirements of this criterion, because the assessments have been scheduled, planned, and conducted by others to serve the purpose of others.

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